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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
EIS-5807 (0112713-1098)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

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Signature _____

Typed or printed name _____

Application Number	Filed
10/059,929	January 29, 2002

First Named Inventor
Tuan Bui, et al.

Art Unit	Examiner
3626	Dilek B. Cobanoglu

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 58,819.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

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January 5, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Tuan Bui, et al.
Appl. No.:	10/059,929
Conf. No.:	8386
Filed:	January 29, 2002
Title:	SYSTEM AND METHOD FOR OPERATING MEDICAL DEVICES
Art Unit:	3626
Examiner:	Dilek B. Cobanoglu
Docket No.:	EIS-5807 (112713-1098)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

This request and the following remarks are submitted in response to the interpretation of the prior art in the August 5, 2008 Final Office Action ("Office Action") and the November 24, 2008 Advisory Action. Such interpretation rises to the level of clear error, making this case proper for pre-appeal review. This request is filed contemporaneously with a form PTO/SB/33, "Pre-Appeal Brief Request for Review," a form PTO/SB/31, "Notice of Appeal," and a Petition for Two Month Extension of Time. Please charge Deposit Account No. 02-1818 for the Notice of Appeal fee set forth under 37 C.F.R. §41.20(b)(1), the Petition for Two Month Extension of Time, and any other fees due in connection with this request.

Claims 1 to 191 are pending and rejected under 35 U.S.C. § 102(e) as anticipated by United States Patent No. 6,790,198 to White et al. ("*White*"). Applicants respectfully submit that the Examiner's rejection of Claims 1 to 191 in view of *White* rises to the level of clear error.

One of the benefits of the claimed system is that bypassing computers at the patient location (e.g., having operating parameters sent directly from a central computer), along with other comparison steps discussed in detail below, helps eliminate human error. (See page 10, lines 21 to 27 of the application). *White* does not teach these advantageous steps as discussed next.

White is generally directed to a wireless communication system between an IV medication infusion pump and a hospital information management system ("HIMS"). A transmitter is connected to the pump, which transmits a signal representing pre-selected pump operation characteristics to the HIMS. The HIMS includes a receiver configured to receive the signal and a processor capable of storing and displaying the pump operation characteristics. The pump is also configured to receive pump operation characteristics.

In the embodiment of *White* cited in the Office Action, a doctor inputs an order for patient medication to be administrated by the pump into the doctor's order transmitter, which is capable of manually receiving an input (e.g., via a keyboard). Column 6, line 6 to column 7, line 18 of *White*, explains:

> In one such embodiment ***the doctor's order signal 87 is received at receiver 61 by the HIMS 60 for storage and/or for comparison to the actual operation characteristics*** as represented by the signal 49 transmitted from the IV pump 10. The storage and comparison may be carried out using an appropriate CPU 57. The pump 10 may also be provided with wireless signal receiver 51 to receive the doctor's order wireless signal 87 directly. Alternatively, the HIMS may also be provided with a transmitter 65 to provide to the IV pump 10, a HIMS wireless signal 67 that may include a retransmission of the doctor's order wireless signal 87, selected portions of the instructional content of the doctor's order 82, or other data or instructions such as instructions input at keyboard 59 or stored at CPU 57. The receiver at the IV pump 10 is capable of receiving such data or instructions for entry into the IV pump controls 43. ***At the pump*** data or instructions entry and pump activation will be according to appropriate safeguard, such as verification by the nurse or other health care professional responsible for the particular hospital patient. [Emphasis added].

In all embodiments disclosed in *White*, a nurse manually verifies any instruction sent to or entered into the pump. For example, referring to the flowchart in Fig. 5 of *White*, at box 79, the nurse validates that the instructions received by the pump are correct and begins the infusion.

In *White*, a nurse has to manually review each instruction and validates it prior to beginning the treatment. For example, *White* states:

- Such infusion data and pumping characteristics will nevertheless need to be validated by the nurse, in order to maintain the integrity of the system (column 8, lines 59 to 61).

- The nurse may use a hand-held communication unit 98 to manually enter information from a label on an IV container. The nurse may transmit the instructional data to the IV pump and upon confirming the patient,

medication and pumping data match, the nurse may initiate IV pumping (column 9, lines 35 to 40).

- Again, upon confirming the information loaded into the IV pump, the nurse may activate pumping operations (column 9, lines 57 and 58).

- If all of the required infusion information is validated by the nurse, then the infusion may be initiated according to the accurately scanned infusion information . . . (column 12, lines 24 to 27).

Claim 1, on the other hand, includes the steps of determining if a second patient identifier (e.g., from a patient wristband) is equivalent to a third patient identifier (e.g., from a medication label) and sending a medication identifier to a first computer (e.g., a central hospital computer) ***if the second patient identifier is equivalent to the third patient identifier***, and determining if the third patient identifier is equivalent to a first patient identifier (e.g., a patient identifier manually entered into the central hospital computer) and sending the operating parameter from the first computer to the medical device ***if the third patient identifier is equivalent to the first patient identifier***, where the operating parameter does not pass through the second computer. The Office Action does not identify three distinct patient identifiers in *White*, let alone the claimed three-way cross check, as discussed below.

The Office Action references column 6, line 66 to column 7, line 2 of *White* as showing the step of determining if a second patient identifier is equivalent to a third patient identifier. This passage of *White* only discloses comparing ***a doctor's order*** to ***operating parameters*** of the pump. Nowhere does *White* disclose or suggest determining ***if a second patient identifier is equivalent to a third patient identifier.***

The Office Action references column 4, lines 42 to 52 of *White* as showing the step of determining if a third patient identifier is equivalent to a first patient identifier. This passage of *White* only discloses that the pumps have a unique identification, and that information regarding the patient treated by a pump may be identified. Page 5 of the Office Action also references column 9, lines 47 to 53 of *White* regarding this step, which discloses a nurse entering a patient and IV medication identification into a hand-held unit. Nowhere does *White* disclose or suggest determining ***if a third patient identifier is equivalent to a first patient identifier.***

The Advisory Action also refers to column 15, lines 3 to 34 of *White* as disclosing the above comparisons. But the passage merely discloses that a nurse is prompted to scan infusion

information from a container only if a patient ID has been scanned from a patient's wristband. Nowhere does this passage disclose determining if a second patient identifier is equivalent to a third patient identifier and determining if a third patient identifier is equivalent to a first patient identifier. In fact, this passage makes no mention of any comparisons.

The combination of the structure and corresponding functional comparisons between the structure in Claim 1 and the operating parameter not being sent through the second computer (i.e., a hand-held unit) help eliminate human error in the administration of a treatment to a patient. *White* does not disclose the automated nature and detailed checks of the claimed system and method, which requires a nurse to verify all treatments and treatment parameters. For at least the above reasons, the rejection of Claims 1 to 20 as anticipated by *White* rises to the level of clear error.

Claims 21 to 191 provide substantially similar elements to those discussed above with respect to Claim 1 and the rejection of those claims rises to the level of clear error for the same reasons.

Claims 67 to 114 additionally provide that ***a latest operating parameter*** is compared to a first operating parameter. The latest operating parameter is provided to the medical device under certain conditions. *White* does not disclose or suggest such features. The Office Action makes no attempt to specifically identify any such disclosure in *White*. For this additional reason, the rejection of Claims 67 to 114 as anticipated by *White* rises to the level of clear error.

Claim 146 includes the steps of reading a medication identifier at a remote location, the medication identifier including a second patient identifier and ***a first medical device identifier***; reading ***a second medical device identifier*** at the remote location, the second medical device identifier being affixed to the medical device; and receiving an operating parameter for the medical device from a central location, if a first patient identifier is equivalent to a second patient identifier, and ***if the medical device identifier and the second medical device identifier are equivalent***. [Emphasis added]. Claim 160 includes similar features. *White* does not disclose or suggest such features. Again, the Office Action makes no attempt to specifically identify any such disclosure in *White*. Accordingly, the rejection of Claims 146 to 160 as anticipated by *White* rises to the level of clear error.

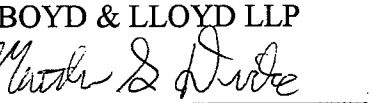
Claim 155 provides a digital assistant designed to trigger the transmission of an operating parameter for a medical device from a central location to the medical device, ***if a first patient identifier is equivalent to a second patient identifier.*** [Emphasis added]. *White* does not disclose such a digital assistant. For this additional reason, the rejection of Claim 155 and dependent Claims 156 to 159 as anticipated by *White* rises to the level of clear error.

Claim 165 includes storing a first operating parameter at a central location, the first operating parameter associated with a first patient identifier; accepting a second operating parameter into a medical device, the medical device being at a remote location; accepting the first patient identifier into the medical device; sending the second operating parameter and the first patient identifier to the central location; and ***sending an alarm to the remote location, if the first operating parameter is not equivalent to the second operating parameter.*** [Emphasis added]. Claims 175 and 182 include similar claim language. *White* does not disclose such steps. For this additional reason, the rejection of Claims 155, 175 and 182 and the claims depending therefrom as anticipated by *White* rises to the level of clear error.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

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